REMARKS

This Response is timely filed within three months of the mailing date of the latest Office Action. Accordingly, no fee is required. 37 CFR § 1.134-1.136.

Claims 104-109, 115, and 120-135 are pending in this application, of which claims 104-109 are withdrawn from consideration. Applicants acknowledge the Examiner's indication that the restriction requirement as to claims 132-135 is withdrawn. Reconsideration of the application in view of the following remarks is respectfully requested.

I. THE CLAIMS ARE PATENTABLE OVER STEVENS IN VIEW OF GROSS

Claims 115, and 120-135 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,885,238 to Stevens, *et al.* (hereinafter "Stevens") in view of U.S. Patent No. 5,407,434 to Gross (hereinafter "Gross"). This rejection is respectfully traversed.

Claim 115 is directed to a method of repairing an aneurysm in a vessel using at least two sheath devices. The recited method comprises the steps of: introducing at least a portion of the sheath devices into the vessel; inserting a repair apparatus through a sealing cavity containing a self-sealing gel-like material disposed in at least one of the sheath devices; repairing the aneurysm in the vessel; and removing the repair apparatus from the sheath devices and the sealing cavity.

Claim 124 is directed to a method of reducing the loss of blood from a vessel using a first sheath device in communication with a second sheath device, at least one of the first and second sheath devices comprising a sealing cavity. The recited method comprising the steps of: introducing the first sheath device into the vessel; introducing

the second sheath device into the vessel; inserting at least one repair apparatus through the sheath devices and the sealing cavity; performing a surgical procedure; and removing the repair apparatus from the sheath devices and the sealing cavity.

Claim 126 is directed to a method of reducing the loss of blood during the surgical repair of an aneurysm using a first sheath in communication with a second sheath device, the first and second sheath devices each comprising a housing with a first end portion, a second end portion, a hollow interior spanning from the first end to the second end portion, and a sealing cavity proximate to the second end portion of at least one of the sheath devices. The method recited in Claim 126 comprises the steps of: introducing the first end portion of the first sheath device proximate to the aneurysm through an artery; introducing the first end of the second sheath device distal to the aneurysm through the artery; inserting at least one repair apparatus through the second sheath device, the first sheath device, and the sealing cavity; repairing the aneurysm; and removing the repair apparatus from the second and first sheath devices and the sealing cavity.

Claim 132 is directed to an introducer sheath system for use during a surgical procedure. The system recited in Claim 132 comprises: at least two introducer sheath devices, the introducer sheath devices each comprise a housing having a passageway accommodating at least one surgical component therein; a sealing cavity in communication with the housing of at least one sheath device, the sealing cavity containing a biocompatible self-sealing material forming a seal around the surgical components as the components are inserted and removed through the sealing cavity.

The remaining claims pending in the application depend from either Claims 115, 124, 126, or 132 and include at least all the limitations recited therein.

Taken alone or in combination, neither Stevens nor Gross teach the claimed subject matter of the present invention. Although Stevens is directed generally to devices and methods for performing cardiovascular procedures, Stevens does not teach a method of repairing an aneurysm in a vessel or a method of reducing the loss of blood from a vessel as recited in the present claims. Moreover, Stevens does not teach providing a device having a sealing cavity, and inserting a repair apparatus through the sealing cavity.

In the present Office Action, the Examiner states that "Stevens teaches treatment of aneurysms (col. 17, line 9) using two sheaths (broadly shown in figure 6, the reference generally teaching that any of a number of instruments may be inserted through the sheaths; see col. 17, line 9)." Notably, the Examiner fails to identify a sealing cavity in Stevens. Figure 6 discloses an occluding catheter having a balloon **11** and a distal port **41**, and a heart replacement valve delivery catheter **75** advanced through the occluding catheter. See Fig. 6; Col. 26, l. 45 – Col. 27, l. 3. The catheter disclosed in Stevens has an open distal port **41** through which fluids are passed. See Fig. 6, Col. 21, ll. 25-40. The disclosed device does not teach a sealing cavity and the insertion of a repair apparatus through the sealing cavity. Rather, the catheter described in Stevens, and its function of openly passing fluids, actually teaches away from a device and method that provides a sealing cavity through which instruments, but not fluids, may pass, as presently claimed.

Further, Gross does not teach the subject matter of the present invention. Gross suggests only a single thoracentesis device **10** that includes "an elongated flexible catheter **14** having a leading end **16** formed with one or more radial ports or openings **18** which allow for fluid or air communication with the body cavity to which the leading end is inserted" and its method of use. See Gross, Col. 2, ll. 42-47; Col. 5, ll. 10-31. Gross is completely silent, however, to a method of repairing an aneurysm in a vessel or a method of reducing the loss of blood from a vessel as recited in the present claims. Moreover, Stevens does not teach providing a device having a sealing cavity, and inserting a repair apparatus through the sealing cavity.

In order to establish a *prima facie* showing of obviousness under Section 103, the Examiner must set forth three basic criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the reference teachings. *See* MPEP § § 706.02(j), 2142 (8th ed., 2nd Rev., 2004). Second, there must be a reasonable expectation of success. *Id.* Finally, the prior art reference (or the references when combined must teach or suggest all of the claim limitations. *Id.*

The Examiner fails to establish a *prima facie* showing of obviousness. The Examiner has failed to provide any meaningful explanation of the required motivation for combining Stevens and Gross. The required motivation is presumed in the latest Office Action from the mere fact that Stevens discloses a hemostatic valve and "that it would have been obvious to one of ordinary skill in the art to modify the reference of Stevens by including the gel-like valve of Gross as a substantially equivalent alternative to the

hemostatic valve." This assertion, however, does not provide the required motivation. Stevens and Gross are directed to entirely different medical fields, and are classified in entirely different sub-classes of the USPTO database. The only apparent motivation for combining the references arises from Applicant's disclosure and the claimed invention itself, which constitutes impermissible hindsight motivation and cannot be relied upon as a reason to combine references. *See, e.g., In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

Further, although Gross discloses the use of a viscous material in a thoracentesis device, Gross is expressly directed to "a thoracentesis device which prevents air entry into the pleural cavity and lung puncture during use." See Gross, Col. 1, ll. 5-10. The obviousness of using a second thoracentesis device disclosed in Stevens in communication with a first device disclosed in Gross is absent where the risk of air entering the pleural cavity and the threat of lung puncture and collapse increase significantly with the addition of a second device. As such, there is no basis for a reasonable expectation of success that Gross would operate properly when combined with the device of Stevens.

For at least the reasons set forth above, Applicants respectfully submit that Stevens and Gross, taken alone or in combination, fail to disclose, teach or suggest the invention claimed by Applicants. Reconsideration and withdrawal of the rejections are respectfully requested.

II. CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that the claims of the present invention define subject matter patentable over the references cited by the Office and that the application is in condition for allowance.

Should the Office believe that anything further is desirable to place the application in better condition for allowance, the Office is invited to contact Applicants' undersigned attorney at the below listed telephone number.

The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to deposit account number 03-2469. Moreover, if the deposit account contains insufficient funds, the Commissioner is hereby invited to contact Applicant's undersigned representative to arrange payment.

Respectfully submitted,

Date: September 6, 2005

JOHN N. COULBY, Reg. No. 43,565
MARK W. RYGIEL, Reg. No. 45,871
COLLIER SHANNON SCOTT, PLLC
3050 K Street, N.W., Suite 400
Washington, D.C. 20007
(202) 342-8400